Revised 510(k) Summary

Date Prepared: *Revised September 4, 2013*

Device Trade Name: StitchKit®

Common Name: Suture Delivery Canister

SEP 0 5 2013

Submitter: Origami Surgical, LLC
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Madison, NJ 07940

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Classification: Class: II
Panel: General and Plastic Surgery

Regulation: 878.5035 Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene
Product Code: NBY, GCJ, NAY

Intended Use: The StitchKit® device facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The ePTFE suture contained within StitchKit® is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

Description of Device

The StitchKit® device is a sterile, single-use plastic canister that is pre-loaded with six strands of non-USP ePTFE suture, (diameter approx. 0.294 mm < dia <0.383 mm, and strand length approx. 20 cm). The device facilitates robotically assisted endoscopic surgery by introducing these multiple strands of suture to the surgical field all at once within the plastic canister. The surgeon can then retrieve the suture strands from the canister one at a time. The device is sized to be passed through a ≥12 mm trocar. As suturing is completed with each strand, used needles are deposited into a compartment within the StitchKit® canister. Once the surgeon has finished all suturing, the device is removed with the used needles still inside. It is supplied sterile in a plastic tray with Tyvek® lid.

Summary of Technological Characteristics vs. Predicate

The predicates for the StitchKit® device are the LSI Solutions Suture Placement Device (K981531); and Gore-Tex® Nonabsorbable ePTFE Surgical Suture (reference 21 CFR Part 878, Docket No. 94P-0347).

The LSI Solutions Suture Placement Device is a medical device that is used to deliver suture materials to the site of an endoscopic surgery, approximate tissue, and remove used needles afterwards. The StitchKit® device has a narrower intended use than the LSI Solutions Device in that it does not contain mechanisms which accomplish the passing of needles through tissue. However, both devices deliver suture materials to the site of an endoscopic surgery, and remove used needles afterwards.

The initial version of the StitchKit® which is the subject of this submission is provided to the user preloaded with 6 strands of a commonly used nonabsorbable ePTFE surgical suture, purchased from its manufacturer. While this suture has a very broad intended use, when loaded into the StitchKit® device, it is configured to be delivered endoscopically through a surgical trocar for use in Robotic Surgery. This is a subset of the intended use for the suture in general.

The technological characteristics for the StitchKit® device are similar to the predicate LSI Solutions Suture Placement Device in that the StitchKit® is a plastic container that contains suturing materials, and this predicate device *includes* a plastic container containing suturing materials (its cartridge). The technological characteristics for the StitchKit® device are similar to those for the predicate Gore-Tex® Nonabsorbable ePTFE Surgical Suture in that the StitchKit® device contains nonabsorbable ePTFE surgical suture that has been purchased from its manufacturer and modified only in that it has been cut to a new length and packaged.

Test Data

The performance testing performed for this device includes:

- Biocompatibility
- Shelf-life testing
- Packaging validation
- Sterilization validation
- Suture testing per USP methods including knot-pull testing, diameter, and needle attachment
- Suture length

- Device physical dimensions including weight and size
- Suture dispensing force
- Tensile evaluation of the strength of key components including foam pull-out, suture-holder base pull-out, and disposal compartment cover pull-out
- Retrieval string tensile strength
- Hinge strength

This testing has demonstrated that the StitchKit® device meets its design input requirements, including that the suture's key characteristics are unaffected by its cutting to length, packaging and sterilization.

Conclusion

Based on the Indication for Use, technological characteristics, test data, and comparison to its predicate device we conclude that the StitchKit® device has been shown to be substantially equivalent to its legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

John Gillespie
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September 5, 2013

Re: K123811
Trade/Device Name: StitchKit®
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: Class II
Product Code: NBY, GCJ, NAY
Dated: July 29, 2013
Received: August 8, 2013

Dear Mr. Gillespie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K123811**

Device Name: **StitchKit®**

Indications for Use:

The StitchKit® device facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The ePTFE suture contained within StitchKit® is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

Prescription Use _X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123811